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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,651	03/29/2004	Peter Gilbert	J-3776A	2445

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EXAMINER	
PETERSEN, CLARK D	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,651	GILBERT ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8, and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 16 January 2007, in which claims 6, 7, and 9 were canceled, claims 1, 5, and 10 were amended, and claims 14-17 were added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This is a rejection previously presented in the Office Action 17 Oct 2006, and slightly modified as necessitated by Applicants' amendment.

Claims 1-5 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljemark et al (Infection and Immunity, 1981). Liljemark et al teach a method of testing aggregation and adherence of oral streptococci to hydroxyapatite beads. Specifically, they compare the effect of bacterial aggregation in response to added lectins or saliva; they

demonstrate that it is possible to induce bacterial aggregation in individual species in response to concanavalin A, for example (see p. 936, col. 1, for example).

Liljemark et al do not expressly teach the combination of two different types of oral streptococci in an aggregation by inducing agglutination with Concanavalin A. However they teach that the *Streptococcus mitis* and *Actinomyces viscosus* can be coaggregated and induced to bind to hydroxyapatite beads coated with saliva (see Fig. 7, p. 939, for example). They also state that the aggregating effects of the Streptococcus species in response to concanavalin A was very similar to that induced by saliva (see p. 938, col. 1, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lectins in a method taught by Liljemark of coaggregating bacteria on hydroxapatite beads, because Liljemark teaches that lectins and saliva have very similar profiles in inducing bacterial aggregation, and Liljemark also teaches that heterogeneous aggregates are readily induced by saliva. One would have been motivated to do so for the expected benefit of producing heterogeneous bacterial aggregates relevant to the study of oral bacteria biofilms.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Claims 1-5, 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljemark et al and Hussain et al (J Med Microbiol, 1992).

This is a new rejection, modified slightly from rejections in the Office Action mailed 17 Oct 2006, slightly amended as necessitated by Applicants' amendment.

Hussain et al teach a method of growing a bacterial slime comprising coagulase negative streptococci isolates. They then expose the slime to a battery of antibiotics and measure the inhibitory effect on bacterial metabolism through measurement of uptake of radiolabeled glucose in isolated slime fragments (see Materials and methods, p. 64, for example). Hussain et al note that some antibiotics had no effect on biofilm formation, but bacterial metabolism could still be measured through radiolabeled glucose uptake (see Results, p. 67; see Fig. 2, as examples). Therefore, their experiments read on exposing a bacterial aggregate to a biocide and measuring viability of the bacteria within the aggregate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure antibiotic action of a substance against cells within a bacterial aggregate as taught by Hussain et al, using an aggregate formed by addition of lectins to a bacterial suspension taught by Liljemark et al, because Liljemark et al teaches that it is possible to form bacterial aggregates through addition of lectins such as concanavalin A, and Hussain et al teach that it is possible to expose bacterial aggregates to antibiotics and measure their metabolic function. One would have been motivated to do so because it is well known in the art that response of bacteria in aggregates to antibiotics is different than the response of individual, suspended bacteria.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljemark et al (Infect Immun, Mar 1981).

This is a new rejection necessitated by Applicants' amendment.

As previously discussed, Liljemark et al teach a method of creating aggregates of bacteria by adding the lectin Concanavalin A. They also teach that these aggregates bind together spontaneously when commingled in phosphate buffer (see p. 936, Materials and Methods, "Adherence of preformed bacterial aggregates"; see p. 938, "Adherence of coaggregating bacteria", for example). Liljemark et al also teach that bacterial aggregation behavior changes in response to concanavalin A concentration (see Fig. 2, p. 937, for example). They teach that larger aggregates occur with increased concentrations of concanavalin A (see p. 937, col. 1, paras 1 and 2, for example). They teach however that there is a saturation effect, wherein adherence decreases above a certain concentration.

A person of ordinary skill in the art at the time the invention was made would have been motivated to create a bacterial aggregate, and modulate concanavalin concentration to obtain different aggregation results because Liljemark et al teach that concanavalin A is effective in binding bacteria together, and that different preaggregated bacterial species will spontaneously aggregate together; adding more concanavalin A would be an effective alternative, because Liljemark et al teach in the first place that Concanavalin A is an effective bacterial aggregant.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare a multilayer bacterial aggregate using Concanavalin A with steps in which concanavalin A concentration is increased or reduced.

Response to arguments - 35 USC § 102/103

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 102(b) as being anticipated by Jones (J Clin Pathol, 1993). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 102(b) as being anticipated by Liljemark et al (Infect Immun, 1981). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 103(a) as being anticipated by Jones (J Clin Pathol, 1993) in view of Hussain et al (J Med Microbiol, 1992). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 103(a) as being anticipated by Jones (J Clin Pathol, 1993) in view of Lamont and Rosan (Infect Immun, 1990). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 103(a) as being anticipated by Jones (J Clin Pathol, 1993) in view of Lamont and Rosan (Infect Immun, 1990) and Wu et al (J Bacteriol, 1995). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-4 and 10-12 under 35 USC 102(b) as being anticipated by Jones (J Clin Pathol, 1993) in view of Lamont and Rosan (Infect Immun, 1990) and Wu et al (J Bacteriol, 1995) and Hussain et al (J Med Microbiol, 1992). Based Applicants' amendment, this rejection is withdrawn.

Applicants traverse the rejection of Claims 1-5 and 10-12 under 35 USC 102(b) as being anticipated by Liljemark et al (Infect Immun, 1981). This rejection is maintained for reasons set forth above and discussed below.

Applicants argue that Liljemark et al nowhere teach co-aggregation of two bacteria accomplished with added Concanavalin A.

Liljemark teach that both types of bacteria can be aggregated with Concanavalin A. They also teach that these two types of bacterial aggregates spontaneously co-aggregate. Based on the fact that it is already established that the bacteria can initially aggregate in the presence of Concanavalin A, and that the two species can co-aggregate, it would be obvious to add Concanavalin A to bacteria to further induce aggregation, whether it is between species or within a species. Applicants have cited p. 936 to rebut Examiner's arguments (p. 936, end of col 1 to beginning col 2). It is true that Liljemark et al do not state that coaggregation occurs in the presence of Concanavalin A. However based on the fact that both species aggregate in the presence of Concanavalin A, and in fact do not need this lectin to coaggregate, it would be obvious as a functional matter to add Concanavalin A to further the process. Liljemark teaches two fundamental inventive steps: bacteria can be aggregated with lectins, and different species of

bacteria coaggregate together. It would not be an unexpected result that different species of bacteria would coaggregate in the presence of lectin. Therefore the rejection of claims 1-5 and 10-12 as being obvious over Liljemark et al is maintained.

Regarding the argument that Liljemark does not teach yeast or fungi, it is noted that Applicants have not canceled the species of bacteria from Claim 11. Therefore the rejection of Claim 11 over Liljemark is maintained.

Examiner has presented a new rejection of Claims 1-5, 8 and 10-13 over Liljemark (discussed above) in view of Hussain (J Med Microbiol, 1992). Applicants traversed the rejection of claims 1-4, 8, and 10-13 over Jones in view of Hussain et al.

Applicants argue that the teachings of Hussain et al do not lead one skilled in the art to the instant invention. Applicants argue that Hussain et al only use lectin to detect slime production, and that they only teach the effect of antibiotics on slime production.

Hussain et al teach the study of a bacterial aggregate, namely biofilm. Although the geometry is different, that is not the scope of the instant set of claims. Hussain et al do, in fact, measure the viability of their biofilm (see p. 63, col. 2, last paragraph, to p. 64, col. 2, first paragraph). Hussain et al test the radiolabeling of bacteria as well as radiolabeling of extracellular slime; the radiolabeling of bacteria is a measure of metabolism that indicates viability (see Table IV, p. 66; see "[^{14}C]glucose asay for quantitation of adherent bacteria + slime", p. 63, col. 2, last paragraph; see "Effect of 0.5 MIC on biofilm formation", p. 64, col. 1, as examples). Hussain provides the teaching that one can test the viability of a bacterial

aggregate in the presence of bacteriocides. Therefore the rejection over Hussain et al is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
3/28/2007

JON WEBER
SUPERVISORY PATENT EXAMINER